

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

**CERTIFICATE OF NEED ~~(CON)~~ REVIEW STANDARDS FOR
URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES/~~UNITS~~**

(By authority conferred on the ~~Certificate of Need~~CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve a urinary extracorporeal shock wave lithotripsy service/unit.

(2) ~~A urinary~~ extracorporeal shock wave lithotripsy ~~service/unit~~ is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, ~~9, 11, 12, 13~~, 14, and 15, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use sections ~~9-10~~ and ~~10-11~~, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "~~Acquire~~ ACQUISITION OF an existing UESWL service ~~/unit~~" means obtaining possession or control of an existing UESWL service ~~/AND ITS unit(S)~~ by purchase, lease, donation, or other comparable arrangement.

(b) "Central service coordinator" ~~OR "CSC"~~ means the organizational unit that has operational responsibility for a mobile UESWL SERVICE AND ITS unit(S) and that is a legal entity authorized to do business in the state of Michigan.

(c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 ~~et seq.~~ of the Michigan Compiled Laws.

~~—(e) "Comparative group" means the applications that have been grouped for the same distinct category in the same planning area and are being reviewed comparatively in accordance with the Certificate of Need rules.~~

(~~F~~) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes, but is not limited to:

(i) A urology service that provides skilled and experienced ureteroscopic stone removal procedures and

(ii) Experienced interventional radiologic support.

(F) "COMPREHENSIVE KIDNEY STONE TREATMENT CENTER" OR "CKSTC" MEANS A FACILITY THAT EMPLOYS A MULTI-DIMENSIONAL APPROACH TO THE TREATMENT OF KIDNEY STONES. IN ADDITION TO A FIXED LITHOTRIPSY UNIT, A CKSTC USES HOLMIUM LASERS, UROLOGY ENDOSCOPES, AND OTHER STONE RETRIEVAL DEVICES TO PERFORM CYSTOSCOPIES, URETEROSCOPIES, AND NEPHROSTOLITHOTOMIES. A CKSTC HAS SERVICE AVAILABILITY 24 HOURS A DAY. ITS MEDICAL STAFF IS DRAWN FROM A MULTI-COUNTY AREA OR IS COMPRISED OF FULL-TIME MEDICAL SCHOOL FACULTY. A CKSTC SERVES AS SOURCE OF EXPERTISE AND RARELY-USED KIDNEY STONE DEVICES FOR OTHER LOCAL PROVIDERS.

(g) "Department" means the ~~state agency known as the~~ Michigan Department of Community Health

(MDCH).

~~(h) "Department inventory" means the list set forth in Appendix A and maintained by the Department;~~
~~(i) UESWL services/units operating pursuant to a valid Certificate of Need issued under Part 222 or former Part 221 and (ii) UESWL services/units that are not yet operational but have a valid Certificate of Need issued under Part 222. The inventory shall not include a host site approved pursuant to Section 5(2).~~

(iH) "Existing UESWL unit" means a UESWL unit that has ~~Certificate of Need~~ CON approval to operate in Michigan and is in operation on the date an application is submitted to the Department.

(I) "EXPAND A UESWL SERVICE" MEANS THE ADDITION OF ONE UESWL UNIT AT AN EXISTING UESWL SERVICE.

(j) "Hospital" means a health facility licensed under Part 215 of the Code.

(k) "Host site" means the site at which a mobile UESWL unit is authorized to provide UESWL services.

(l) "Initiate a UESWL service/unit" means to begin operation of a UESWL unit, whether fixed or mobile, at a site that ~~is not listed on the Department inventory as of the date an application is submitted to the Department~~ DOES NOT OFFER (OR HAS NOT OFFERED WITHIN THE LAST CONSECUTIVE 12-MONTH PERIOD) APPROVED UESWL SERVICES. The term does not include the acquisition or relocation of an existing UESWL service/unit or the renewal of a lease.

(m) "Licensed site" means either of the following:

(i) In the case of a single site health facility, the location of the facility authorized by license and listed on that licensee's Certificate of Licensure.

(ii) In the case of a health facility with multiple sites, the location of each separate and distinct health facility as authorized by license and listed on that licensee's Certificate of Licensure.

(N) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT. 620, 1396R-6 AND 1396R-8 TO 1396V.

~~(nQ) "Michigan Inpatient Database" or "MIDB" means the database that is compiled by the Michigan Health and Hospital Association with the authorization of and oversight by outside agencies including the Department OR SUCCESSOR ORGANIZATION.~~ The database consists of inpatient discharge records from all ~~short-term, general-stay~~ Michigan hospitals AND MICHIGAN RESIDENTS DISCHARGED FROM HOSPITALS IN BORDER STATES for a specific calendar year.

~~(oP)~~ "Mobile UESWL unit" means a UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

~~(pQ)~~ "Planning area" means the state of Michigan.

~~(q) "Qualifying project" means each application in a comparative group that has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.~~

(r) "Region" means the geographic areas set forth in Section ~~4213~~.

(s) "Relocate an existing UESWL service/unit" means a change in the geographic location of an existing fixed UESWL service AND ITS unit (S) from an existing site to a different site.

(t) "Relocation zone," for purposes of these standards, means the geographic area that is within a 25-mile radius, within the state of Michigan, of the existing site of the UESWL service/unit to be relocated.

(u) "Renewal of a lease" means extending the effective period of a lease for an existing UESWL unit that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section 2(1)(v), or a change in the parties to the lease.

(v) "Replace/upgrade a UESWL unit" means a change involving all or part of an existing UESWL unit proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion.

(w) "Retreatment" means a UESWL procedure performed on the same side of the same patient within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of a mobile service/unit, the term includes a retreatment performed at a different host site if the initial treatment was performed by the same service.

(x) "Rural county" means a county not located in a metropolitan STATISTICAL area OR MICROPOLITAN STATISTICAL AREAS as ~~that THOSE~~ term S ~~is ARE~~ defined ~~pursuant to~~ UNDER the ~~"Revised~~ Standards ~~FF~~ or Defining Metropolitan AND MICROPOLITAN STATISTICAL Areas Areas in the

111 ~~1990~~ by the Statistical Policy Office of the Office of Information and Regulatory Affairs of the United
112 States Office of Management ~~And And~~ Budget, ~~55-65~~ F.R. ~~PP. 12154-82238~~ (~~March DECEMBER 3027,~~
113 ~~19902000~~) AND AS SHOWN IN APPENDIX C.

114 (y) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the
115 ureter by means of an endoscope; that may or may not include laser technology.

116 (z) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal
117 of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized
118 into sand-like particles, which then may be passed through the urinary tract.

119 (aa) "Urinary extracorporeal shock wave lithotripter" or "UESWL unit" means the medical equipment
120 that produces the shock waves for the UESWL procedure.

121
122 (2) The definitions in Part 222 shall apply to these standards.

123 124 **Section 3. Requirements for all applicants proposing to initiate a urinary extracorporeal shock** 125 **wave lithotripsy service/unit**

126
127 Sec. 3. (1) An applicant proposing to initiate a UESWL service/unit shall demonstrate each of the
128 following:

129 (a) ~~Approval of the proposed UESWL service/unit shall not result in either: more than 5 UESWL~~
130 ~~units in the planning area being listed on the Department inventory or an increase in the number of units~~
131 ~~listed on the Department inventory in excess of 5 in the planning area. An application that meets the~~
132 ~~requirements of Section 3(2) shall not be required to demonstrate compliance with this requirement.~~

133 ~~(b) The capability to provide complicated stone disease treatment on-site.~~

134 ~~(c) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 14.~~

135 ~~(d) Approval of the proposed UESWL unit shall not result in more than 1 fixed UESWL unit at the~~
136 ~~same site.~~

137 (e) The proposed UESWL service/unit shall be provided at a site that provides, or will provide, each
138 of the following:

139 (i) On-call availability of an anesthesiologist and a surgeon.

140 (ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.

141 (iii) On-site IV supplies and materials for infusions and medications, blood and blood products, and
142 pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.

143 (iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator,
144 general radiography and fluoroscopy, cystoscopy, and laboratory services.

145 (v) On-site crash cart.

146 (vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a
147 cardiac intensive care unit.

148 (vii) On-site 23-hour holding unit.

149
150 ~~(2) An applicant that demonstrates all of the following shall not be required to be in compliance with~~
151 ~~the requirement in subsection (1)(a):~~

152 ~~(a) The proposed UESWL unit is a mobile unit.~~

153 ~~(b) At least four of the proposed host sites on the proposed mobile UESWL service/unit are located~~
154 ~~in a region in which UESWL services are not provided, either by means of a fixed or mobile UESWL unit,~~
155 ~~as of the date an application is submitted to the Department.~~

156 ~~(c) At least 400 UESWL procedures are projected when the results of the methodology in Section 14~~
157 ~~are combined for those licensed hospital sites committing MIDB data that are located in a region in which~~
158 ~~UESWL services are not provided, either by means of a fixed or mobile UESWL unit, as of the date an~~
159 ~~application is submitted to the Department.~~

160 ~~(d) At least 100 UESWL procedures are projected in each region in which the proposed mobile~~
161 ~~UESWL unit is proposed to operate when the results of the methodology in Section 14 are combined for~~
162 ~~the following, as applicable:~~

163 ~~(i) All licensed hospital sites committing MIDB data pursuant to Section 15, as applicable, that are~~
164 ~~located in that region.~~

165 ~~(ii) All sites that receive UESWL services from an existing UESWL unit and propose to receive~~

~~UESWL services from the proposed mobile unit and that are located in that region.~~

~~—(3) An application shall not be approved under Section 3(2) if any other application for a mobile UESWL service/unit has been approved under Section 3(2) or if any application for a mobile UESWL service/unit filed pursuant to Section 3(2), other than the application under review, is pending a proposed or final decision or is under appeal pursuant to a final decision.~~

Section 4. Requirements for approval for applicants proposing to replace/upgrade a UESWL unit(s)

Sec. 4. (1) An applicant proposing to replace/upgrade an existing UESWL unit(s) shall demonstrate the following, as applicable:

(a) The UESWL unit proposed to be replaced/upgraded has performed at least 1,000 UESWL procedures per unit during the most recent continuous 12-month period, ~~or most recent annualized 6-month period,~~ for which the Department has verifiable data.

(b) Each UESWL unit at the same site is projected to perform at least 1,000 UESWL procedures per unit per year pursuant to the methodology set forth in Section 14.

(2) An applicant proposing to replace/upgrade a UESWL unit shall demonstrate one or more of the following:

(a) The existing equipment clearly poses a threat to the safety of the public.

(b) The proposed replacement/upgraded UESWL unit offers technological improvements that enhance quality of care, increase efficiency, or reduce operating costs and patient charges.

(3) An applicant that demonstrates that it meets the requirements in subdivision (a), (b), or (c) of this subsection shall not be required to demonstrate compliance with Section 4(1):

(a)(i) The proposed project involves replacing 1 existing fixed UESWL unit with 1 mobile UESWL unit.

(ii) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.

(iii) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 14 are combined for the following, as applicable:

(A) All licensed hospital sites committing MIDB data pursuant to Section 15, as applicable, that are located in the region identified in subdivision (iii).

(B) All sites that receive UESWL services from an existing UESWL ~~unit~~ SERVICE and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subdivision (iii).

(iv) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.

(v) The proposed mobile UESWL ~~service~~ unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 14.

(b)(i) The proposed project involves replacing 2 or more existing fixed UESWL units with 1 mobile UESWL unit.

(ii) The applicant entity is either: a single organization that operates a fixed UESWL ~~unit~~ SERVICE or a joint venture or other arrangement between at least 2 or more organizations that each operates a fixed UESWL ~~unit~~ SERVICE on the date an application is submitted to the Department.

(iii) The proposed mobile UESWL service/~~unit~~ will serve at least 1 host site that is located in a region other than the region or regions in which the fixed UESWL units proposed to be replaced are located currently.

(iv) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 14 are combined for the following, as applicable:

(A) All licensed hospital sites committing MIDB data pursuant to Section 15, as applicable, that are located in the region identified in subdivision (iv).

(B) All sites that receive UESWL services from an existing UESWL unit and propose to receive

UESWL services from the proposed mobile unit and that are located in the region identified in subdivision (iv).

(v) A separate application from each host site is filed at the same time the application to replace the fixed units is submitted to the Department.

(vi) The proposed mobile UESWL ~~service/~~unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 14.

(c)(i) The proposed project involves replacing 3 or more existing fixed UESWL ~~services/~~units with 1 UESWL unit, either fixed or mobile.

(ii) The applicant entity is a joint venture or other arrangement among 3 or more organizations that each operates a fixed UESWL ~~unit~~SERVICE on the date an application is submitted to the Department.

(iii) The combined number of UESWL procedures performed by all of the fixed UESWL ~~services/~~units operated by the organizations that are party to the applicant entity is equal to or greater than 1,000 procedures based on the methodology set forth in Section 14.

(4) An applicant that operates a fixed or mobile UESWL unit that is proposing a project involving the replacement/upgrade of an existing UESWL unit, when the capital costs for that replacement/upgrade are \$125,000 or less, shall not be required to meet the requirements of subsection (1). This subsection shall apply to the review and decision on only 1 application for the replacement/upgrade of each UESWL unit and on only 1 application at each site.

(5) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM SERVICE AND DISPOSED OF OR RENDERED CONSIDERABLY INOPERABLE ON OR BEFORE THE DATE THAT THE REPLACEMENT EQUIPMENT BECOMES OPERATIONAL.

(6) AN APPLICANT WHICH CAN DEMONSTRATE THAT IT IS A CKSTC SHALL NOT BE REQUIRED TO MEET THE REQUIREMENTS OF SECTION 4(1) IF IT CAN DEMONSTRATE THE FOLLOWING:

(A) THE CKSTC HAS PERFORMED AT LEAST 2,000 KIDNEY STONE TREATMENT PROCEDURES DURING THE MOST RECENT CONTINUOUS 12-MONTH PERIOD. FOR THE PURPOSE OF THIS SUBSECTION, COMPREHENSIVE KIDNEY STONE TREATMENT PROCEDURES SHALL BE CALCULATED AS THE SUM OF THE CYSTOSCOPIES (ICD-9-CM CODES 57.0, 57.32, AND 57.33), NEPHROSTOLITHOTOMIES (ICD-9-CM CODES 55.03 AND 55.04), URETEROSCOPIES (ICD-9-CM CODES 56.0, 56.3, AND 56.33), AND UESWL (ICD-9-CM CODE 98.51) PROCEDURES PERFORMED AT THE CKSTC DURING THE MORE RECENT CONTINUOUS 12-MONTH PERIOD.

(B) OF THE COMPREHENSIVE KIDNEY STONE TREATMENT PROCEDURES PERFORMED DURING THE MOST RECENT CONTINUOUS 12-MONTH PERIOD, AT LEAST 500 MUST HAVE BEEN CYSTOSCOPIES, 40 NEPHROSTOLITHOTOMIES, 300 URETEROSCOPIES, AND 200 UESWL PROCEDURES.

Section 5. Additional requirements for approval for mobile UESWL services/~~units~~

Sec. 5. (1) An applicant proposing to begin operation of a mobile UESWL service/~~unit~~ in Michigan shall demonstrate that it meets all of the following:

(a) The proposed mobile UESWL service/~~unit~~ meets the requirements of ~~Section~~Section 3 or 4, as applicable.

(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile UESWL service/~~AND ITS~~ unit(~~S~~) shall be included in the ~~Certificate of Need~~CON application submitted by the central service coordinator.

(2) The requirements of subsection (1)(a) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service/~~AND ITS~~ unit(~~S~~) operates predominantly outside of Michigan and all of the following requirements are met:

(a) The proposed host site is located in a rural county.

(b) All existing and approved Michigan UESWL service/~~AND ITS~~ unit(~~S~~) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a

UESWL mobile service operating predominantly outside of Michigan.

(C) A SEPARATE CON APPLICATION HAS BEEN SUBMITTED BY THE CSC AND EACH PROPOSED HOST SITE.

(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service/~~unit~~ shall demonstrate that it meets the requirements of Section 3(1)(~~eC~~).

(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL ~~unit~~ SERVICE in a region not currently served by that ~~unit~~ SERVICE shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL ~~unit~~ SERVICE is proposing to add a host site when the results of the methodology in Section 14 are combined for the following, as applicable:

(a) All licensed hospital sites committing MIDB data pursuant to Section 15, as applicable, that are located in that region.

(b) All sites that receive UESWL services from an existing UESWL SERVICE AND ITS ~~unit~~ (S) and propose to receive UESWL services from the proposed mobile SERVICE AND ITS ~~unit~~ (S) and that are located in that region.

Section 6. Requirements for approval for applicants proposing to acquire an existing UESWL service/AND ITS ~~unit~~ (S)

Sec. 6. An applicant proposing to acquire an existing fixed or mobile UESWL service/AND ITS ~~unit~~ (S) shall demonstrate that a proposed project meets all of the following:

(1) The project will not result in the replacement of the UESWL unit at the UESWL service to be acquired unless the applicant demonstrates that the requirements of Section 4, as applicable, also have been met.

(2) The project will not result in a change in the site at which the existing UESWL service/AND ITS ~~unit~~ (S) is operated UNLESS THE PROPOSED PROJECT MEETS THE REQUIREMENTS OF SECTION 7.

(3) For an application for the proposed first acquisition of an existing fixed or mobile UESWL service/~~unit~~, for which a final decision has not been issued after the effective date of these standards, an existing UESWL service/~~unit~~ to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The UESWL service/AND ITS ~~unit~~ (S) shall be operating at the applicable volume requirements set forth in Section ~~9-10~~ of these standards in the second 12 months after the date the service/AND ITS ~~unit~~ (S) is acquired, and annually thereafter.

(4) For any application for proposed acquisition of an existing fixed or mobile UESWL service/~~unit~~, except the first application approved pursuant to subsection (3), for which a final decision has not been issued after the effective date of these standards, an applicant shall be required to demonstrate that the UESWL service/AND ITS ~~unit~~ (S) to be acquired performed at least 1,000 procedures in the most recent 12-month period, ~~or most recent annualized 6-month period~~, for which the Department has verifiable data.

~~—(5) An applicant that demonstrates that an application meets the requirements of Section 8, as applicable, shall not be required to demonstrate compliance with this section.~~

Section 7. Requirements for approval for applicants proposing to relocate an existing UESWL service/~~unit~~

Sec. 7. An applicant proposing to relocate its existing UESWL service/AND ITS ~~unit~~ (S) shall demonstrate that the proposed project meets all of the following:

- (1) The UESWL service/~~AND ITS~~ unit(~~S~~) to be relocated is a fixed UESWL unit(~~S~~).
- (2) The UESWL service/~~unit~~ to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
- (3) The proposed project will not result in the replacement of the UESWL ~~service/unit(S) OF THE SERVICE~~ to be relocated unless the applicant demonstrates that the requirements of Section 4, as applicable, also have been met.
- (4) The proposed project will not result in ~~more than 1 fixed UESWL unit~~ AN INCREASE IN THE NUMBER OF FIXED UNIT(S) being operated ~~at the site to which the~~ BY THE UESWL service/~~unit~~ THAT is proposed to be relocated.
- (5) The site to which the UESWL service/~~unit~~ will be relocated meets the requirements of Section 3(1)(e).
- (6) The proposed site to which the UESWL service/~~unit~~ is proposed to be relocated is in the relocation zone.
- (7) The UESWL service/~~AND ITS~~ unit(~~S~~) to be relocated performed at least 1,000 procedures in the most recent 12-month period, ~~or most recent annualized 6-month period~~, for which the Department has verifiable data.
- (8) THE APPLICANT AGREES TO OPERATE THE UESWL SERVICE AND ITS UNIT(S) IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 10 OF THESE STANDARDS. An applicant that demonstrates that an application meets the requirements of Section 8, as applicable, shall not be required to demonstrate compliance with this section.
- Section 8. ~~Requirements for approval for applicants proposing to acquire and relocate an existing UESWL service/unit~~ REQUIREMENTS TO EXPAND A UESWL SERVICE – ALL APPLICANTS**
- Sec. 8. An applicant proposing to ~~acquire and relocate an existing UESWL service/unit shall demonstrate each of the following:~~ EXPAND A UESWL SERVICE, WHETHER FIXED OR MOBILE, UNLESS OTHERWISE SPECIFIED, SHALL DEMONSTRATE THE FOLLOWING:
- (1) ~~The licensed hospital site to which the UESWL service/unit is to be relocated, and the licensed hospital site from which the UESWL service/unit is to be relocated, are both owned by the same legal entity.~~ ALL OF THE APPLICANT' S EXISTING UESWL UNITS, BOTH FIXED AND MOBILE, AT THE SAME GEOGRAPHIC LOCATION AS THE PROPOSED ADDITIONAL UESWL UNIT, HAVE PERFORMED AN AVERAGE OF AT LEAST 1,800 PROCEDURES PER UESWL UNIT DURING THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA. IN COMPUTING THIS AVERAGE, THE DEPARTMENT WILL DIVIDE THE TOTAL NUMBER OF UESWL PROCEDURES PERFORMED BY THE APPLICANT' S TOTAL NUMBER OF UESWL UNITS, INCLUDING BOTH OPERATIONAL AND APPROVED BUT NOT OPERATIONAL FIXED AND MOBILE UESWL UNITS.
- (2) ~~The UESWL service/unit proposed to be acquired and relocated currently is located at a licensed hospital site that will be delicensed within 24 months after the date the application receives a final decision of approval.~~ THE APPLICANT SHALL PROJECT AN AVERAGE OF AT LEAST 1,000 PROCEDURES FOR EACH EXISTING AND PROPOSED FIXED AND MOBILE UESWL UNIT(S) AS A RESULT FROM THE APPLICATION OF THE METHODOLOGY IN SECTION 15 OF THESE STANDARDS FOR THE THE SECOND 12-MONTH PERIOD AFTER INITIATION OF OPERATION OF EACH ADDITIONAL UESWL UNIT WHETHER FIXED OR MOBILE.

(3) ~~The UESWL service/unit shall be relocated within 24 months after the date the application receives a final decision of approval.~~ AN APPLICANT PROPOSING TO EXPAND A MOBILE UESWL SERVICE MUST PROVIDE A COPY OF THE EXISTING OR REVISED CONTRACTS BETWEEN THE CENTRAL SERVICE COORDINATOR AND EACH HOST SITE(S) THAT INCLUDES THE SAME STIPULATIONS AS SPECIFIED IN SECTION 5(1)(B).

~~—(4) The ~~Certificate of Need~~ CON application includes a resolution of the governing body of both the licensed hospital site from which the UESWL unit is proposed to be relocated and the licensed hospital site to which the UESWL unit is proposed to be relocated that commits to all of the following:~~

~~—(a) The licensed hospital site at which the UESWL unit proposed to be relocated currently is located will be delicensed within 24 months after the date the application receives a final decision of approval.~~

~~—(b) The UESWL service/unit shall be relocated within 24 months after the date the application receives a final decision of approval.~~

~~—(c) If the licensed hospital site at which the UESWL unit proposed to be relocated currently is located is not delicensed within 24 months after the date the application receives a final decision of approval, the applicant agrees to take the relocated UESWL unit out of service or relocate the UESWL unit to the licensed hospital site from which it was relocated.~~

~~—(5) The UESWL service/unit to be relocated is a fixed UESWL unit.~~

~~—(6) The UESWL service/unit to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.~~

~~—(7) The site to which the UESWL service/unit will be relocated meets the requirements of Section 3(1)(e).~~

~~—(8) The proposed site to which the UESWL service/unit is proposed to be relocated is in the relocation zone.~~

~~—(9) The proposed project will not result in the replacement of the UESWL service/unit to be relocated unless the applicant demonstrates that the requirements of Section 4, as applicable, also have been met.~~

~~—(10) The proposed project will not result in more than 1 fixed UESWL unit being operated at the site to which the UESWL service/unit is proposed to be relocated.~~

Section 9. Requirements for approval -- all applicants

Sec. 9. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. IF THE REQUIRED DOCUMENTATION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT.

Section 910. Project delivery requirements -- terms of approval for all applicants

Sec 910. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of ~~Certificate of Need~~ CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following quality assurance standards:

(i) Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards

performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.

(ii) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service/~~unit~~, including complication rates, morbidity data, and retreatment rates.

(iii) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.

(iv) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.

(v) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established FACILITY WITH UESWL center SERVICES.

(vi) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.

(vii) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of subdivision (vi), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

(viii) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.

(ix) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(A) Not deny UESWL services to any individual based on inability to pay or source of payment,

(B) Provide UESWL services to any individual based on clinical indications of need for the services, and

(C) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(x) An applicant shall participate in a data collection network established and administered by the Department OR ITS DESIGNEE. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephrotomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or licensed site in a format established by the Department and in a mutually-agreed-upon media. The Department may elect to verify the data through on-site review of appropriate records.

(xi) ~~An THE~~ applicant shall, ~~within 10 days after initiation of the service/unit~~, provide the Department with a notice stating the ~~first date on which~~ the approved UESWL service/ AND ITS unit(S) was initiated IS PLACED IN OPERATION AND SUCH NOTICE SHALL BE SUBMITTED TO THE DEPARTMENT CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES.

(xii) ~~Equipment that is replaced shall be removed from the UESWL service.~~

~~(xiii) An applicant shall agree that the fixed unit or units approved to be replaced by a mobile UESWL unit pursuant to Section 4(3) shall be removed from service on or before the date the mobile UESWL unit begins operation.~~

~~(xiv) An applicant approved pursuant to Section 8 shall agree that, if the UESWL unit is relocated and the licensed hospital site from which it was relocated is not delicensed within 24 months after the date the application receives a final decision of approval, the UESWL unit will either be removed from service or be returned to the site from which it was relocated.~~ AN APPLICANT SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

(3) The operation of and referral of patients to the UESWL service/unit shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

Section ~~10~~11. Project delivery requirements - additional terms of approval for applicants involving mobile UESWL services/units

Sec. ~~10~~11. (1) In addition to the provisions of Section ~~9~~10, an applicant for a mobile UESWL service/unit shall agree that the services provided by the mobile UESWL unit(s) shall be delivered in compliance with the following terms of ~~Certificate of Need~~CON approval:

(a) The volume of UESWL procedures performed at each host site shall be reported to the Department by the central service coordinator.

(b) An applicant with an approved ~~Certificate of Need~~CON for a mobile UESWL service/unit shall notify the Department and the local ~~Certificate of Need~~CON review agency, if any, at least 30 days prior to dropping an existing host site.

(c) Each mobile UESWL service/unit shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile UESWL service/~~AND ITS~~ unit(S) on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile UESWL unit equipment and the vehicle transporting the equipment.

(e) Each host site must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile UESWL service/unit shall operate under a contractual agreement that includes the provision of UESWL services at each host site on a regularly scheduled basis.

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

~~Section 11. Department inventory~~

~~—Sec. 11. Appendix A sets forth the UESWL services/units included in the Department inventory as of the effective date of these standards. Modifications to Appendix A shall be made by the Department based on decisions issued on Certificate of Need applications and approved Certificates of Need.~~

Section 12. Regions

Sec. 12. The counties assigned to each region are as follows:

Region	Counties			
1	Livingston St. Clair	Monroe Washtenaw	Macomb Wayne	Oakland
2	Clinton Jackson	Eaton Lenawee	Hillsdale	Ingham
3	Barry Cass	Berrien Kalamazoo	Branch St. Joseph	Calhoun Van Buren
4	Allegan Mason Newaygo	Ionia Mecosta Oceana	Kent Montcalm Osceola	Lake Muskegon Ottawa
5	Genesee	Lapeer	Shiawassee	
6	Arenac Gratiot Midland Sanilac	Bay Huron Ogemaw Tuscola	Clare Iosco Roscommon	Gladwin Isabella Saginaw
7	Alcona Crawford Gd. Traverse Missaukee Presque Isle	Alpena Charlevoix Kalkaska Montmorency Wexford	Antrim Cheboygan Leelanau Oscoda	Benzie Emmet Manistee Otsego
8	Alger Dickinson Keweenaw Menominee	Baraga Gogebic Luce Ontonagon	Chippewa Houghton Mackinac Schoolcraft	Delta Iron Marquette

Section 13. Additional requirements for applications included in comparative reviews

~~—Sec. 13 (1) Any application subject to comparative review under Section 22229 of the Code or these standards shall be grouped and reviewed with other applications in accordance with the Certificate of Need rules applicable to comparative reviews.~~

~~—(2)(a) All qualifying projects for a UESWL service/unit pursuant to Section 3(1) of these standards shall be ranked from highest to lowest based on the percentage of the medical/surgical indigent volume at the licensed hospital site at which the proposed UESWL service/unit will be provided.~~

~~—(i) In the case of a proposed mobile UESWL service/unit, the medical/surgical indigent volume used for purposes of this subsection shall be the medical/surgical indigent volume for the host site on the proposed mobile service/unit that projected the largest number of UESWL procedures pursuant to the methodology set forth in Section 14.~~

~~—(ii) For purposes of this subsection, “indigent volume” means the ratio of a hospital’s indigent charges to its total charges expressed as a percentage as determined by the Michigan Department of Community Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Program Hospital Provider Manual. The indigent volume data being used for rates in effect on the date an application is submitted to the Department will be used by the Department in determining the ranking of each qualifying project.~~

~~—(b) All qualifying projects for a UESWL service/unit pursuant to Section 3(2) of these standards shall be ranked from highest to lowest based on the number of UESWL procedures projected pursuant to the methodology set forth in Section 14 for all licensed hospital sites located in a region in which UESWL services are not provided, either by a fixed or mobile UESWL unit, as of the date an application is submitted to the Department. For purposes of this subsection, the applications submitted by the proposed host sites in the region in which UESWL services are not provided either by a fixed or mobile UESWL unit that will be served by the same central service coordinator will be considered as a single qualifying project.~~

~~—(3)(a) Each application in a comparative review group shall be reviewed individually to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.~~

~~—(b) If the Department determines that one or more of the competing applications under either Section 3(1) or 3(2) of these standards satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve the qualifying project or projects in order of ranking from highest to lowest pursuant to the rankings determined pursuant to subsection (2)(a) or (2)(b), as applicable, and that, taken together, do not exceed the need as defined in Section 22225(1), being Section 333.22225(1) of the Michigan Compiled Laws.~~

~~—(c) If two or more qualifying projects are determined to have identical rankings under subsection (2)(a) or (2)(b), the Department shall approve the qualifying project or projects for either subsection (2)(a) or (2)(b), as applicable, that, taken together, do not exceed the need as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, in the order in which the applications were received by the Department, based on the date and time stamp placed on the application of Certificate of Need form (form T-150-1.00 or any subsequent replacement form) by the Health Facilities Section (or the administrative unit of the Department responsible for administering the Certificate of Need program) when an application is submitted to the Department. For purposes of this subsection, in the case of a mobile UESWL service/unit proposed pursuant to Section 3(2), the date and time stamp placed on the central service coordinator’s application shall be used.~~

~~—(4) A qualifying project shall not be ranked under specific subsections of Section 13 if information presented in Section 13 is inconsistent with related information provided in other portions of the Certificate of Need application.~~

Section 1413. Methodology for projecting UESWL procedures

Sec. 1413. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section 1514. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence:

(a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 shall be counted.

(b) The result of subsection (a) shall be multiplied by the factor specified in Appendix B-A for each licensed hospital site that is committing its inpatient discharge data to a ~~Certificate of Need~~ CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a ~~Certificate of Need~~ CON application, the products from the application of the methodology for each licensed hospital site shall be summed.

(c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service/unit, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.

(2) For a site or sites that provide UESWL services as of the date an application is submitted to the Department, the actual number of UESWL procedures performed at each site, during the most recent continuous 12-month period for which the Department has verifiable data, shall be the number used to project the number of UESWL procedures that will be performed at that site or sites.

(3) For a proposed UESWL service/unit, the results of subsections (1) and (2), as applicable, shall be summed and the result is the projected number of UESWL procedures for the proposed UESWL unit for purposes of the applicable sections of these standards.

(4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide access to verifiable hospital-specific data and documentation using a format prescribed by the Department.

Section 1514. Requirements for MIDB data commitments

Sec. 1514. (1) In order to use MIDB data in support of an application for UESWL services, an applicant shall demonstrate or agree to, as applicable, all of the following.

(a) A licensed hospital site whose MIDB data is used in support of a ~~Certificate of Need~~ CON application for a UESWL service/unit shall not use any of its MIDB data in support of any other application for a UESWL service/unit for 5 years following the date the UESWL service/unit to which the MIDB data are committed begins to operate. The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a ~~Certificate of Need~~ CON application.

~~(b) A licensed hospital site that is proposing to commit MIDB data is located in a region that, as of the date an application is submitted to the Department, has 3 or fewer sites, either fixed or mobile host sites, that provide UESWL services.~~

~~(c)~~ The licensed hospital site, or sites, committing MIDB data to a ~~Certificate of Need~~ CON application has completed the departmental form(s) that agrees to or authorizes each of the following:

(i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.

(ii) An applicant shall pay all charges associated with verifying the MIDB data.

(iii) The commitment of the MIDB data remains in effect for the period of time specified in subdivision

(1)(a).

~~(d)~~ A licensed hospital site that is proposing to commit MIDB data to an application is admitting

patients regularly as of the date the director makes the final decision on that application under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

(2) The Department shall consider an MIDB data commitment in support of an application for a UESWL service/unit from a licensed hospital site that meets all of the following:

(a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or does not have a valid Certificate of NeedCON to provide, UESWL services, either fixed or mobile, as of the date an application is submitted to the Department.

(b) The licensed hospital site proposing to commit MIDB data is located in a region in which a proposed fixed UESWL service/unit is proposed to be located or, in the case of a mobile unit, has at least one host site proposed in that region.

(c) The licensed hospital site meets the requirements of subsection (1), as applicable.

Section ~~1615~~. Effect on prior planning policies; comparative reviews

Sec. ~~1615~~. (1) These Certificate of NeedCON review standards supersede and replace the Certificate of NeedCON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services/units approved by the Certificate of NeedCON Commission on ~~March 13, 1998~~SEPTEMBER 21, 2001 and effective on ~~May 2, 1998~~NOVEMBER 26, 2001.

(2) Projects reviewed under ~~Section 3(1) of these standards for a UESWL service/unit shall be considered one distinct category and shall be subject to comparative review.~~

~~—(3) Projects for a mobile UESWL service/unit reviewed under Section 3(2) of these standards shall be considered one distinct category and shall be subject to comparative review.~~

~~—(4) Projects reviewed under these standards for acquisition, acquisition and relocation, relocation, renewal of a lease, or replacement/upgrade of a UESWL unit shall not be subject to comparative review.~~

Department Inventory of UESWL Services/Units

Fixed UESWL Services/Units

Butterworth Hospital	Harper Hospital, Inc./Hutzel Hospital (Joint Venture)
Grand Rapids/Kent	Detroit/Wayne
Henry Ford Hospital	University of Michigan Hospitals
Detroit/Wayne	Ann Arbor/Washtenaw
William Beaumont Hospital	
Royal Oak/Oakland	

Mobile UESWL Services/Units

Central Service Coordinator:

Michigan Mobile Lithotripsy, Inc. (Network #23)

Host Sites:

Borgess Medical Center	Bronson Methodist Hospital
Kalamazoo/Kalamazoo	Kalamazoo/Kalamazoo
Genesys Health System	Oakwood Hospital
Flint/Genesee	Dearborn/Wayne
Munson Medical Center	St. John Hospital
Traverse City/Grand Traverse	Detroit/Wayne
Sparrow Hospital	Doctors Hospital of Jackson
Lansing/Ingham	Jackson/Jackson

Central Service Coordinator:

Mobile Lithotripsy Network (Network #74)
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Host Sites:

Bay Medical Center	Hurley Medical Center
Bay City/Bay	Flint/Genesee
Lapeer Regional Hospital	McLaren Regional Medical Ctr
Lapeer/Lapeer	Flint/Genesee
MidMichigan Medical Center	Munson Medical Center
Midland/Midland	Traverse City/Grand Traverse
Northern Michigan Hospital	St. Mary's Ambulatory Care Ctr
Petoskey/Emmet	Saginaw/Saginaw
West Branch Regional Med Ctr	
West Branch/Ogemaw	

760 APPENDIX A--continued
761
762 ~~The Department inventory does not include mobile host sites approved pursuant to Section 5(2). The following~~
763 ~~list identifies mobile host sites approved pursuant to Section 5(2):~~
764
765 Mobile Host Site(s) Approved Pursuant to Section 5(2)
766
767 ~~Marquette General Hospital~~
768 ~~Marquette/Marquette~~
769

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section 14(1)(b) used for calculating the projected number of UESWL procedures shall be 0.~~724~~805.

(2) The Department may amend Appendix ~~B~~A by revising the factor in subsection (1) in accordance with the following steps:

(a) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 for the most recent year for which Michigan Inpatient Database information is available to the Department.

(b) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (a).

(c) Divide the number of UESWL procedures determined in subsection (b) by the number of inpatient records determined in subsection (a). The result is the revised factor for calculating UESWL procedures.

(3) The Department shall notify the Commission when this revision is made and the effective date of the revision.

CON REVIEW STANDARDS
FOR UESWL SERVICES

RURAL MICHIGAN COUNTIES ARE AS FOLLOWS:

<u>ALCONA</u>	<u>HILLSDALE</u>	<u>OGEMAW</u>
<u>ALGER</u>	<u>HURON</u>	<u>ONTONAGON</u>
<u>ANTRIM</u>	<u>IOSCO</u>	<u>OSCEOLA</u>
<u>ARENAC</u>	<u>IRON</u>	<u>OSCODA</u>
<u>BARAGA</u>	<u>LAKE</u>	<u>OTSEGO</u>
<u>CHARLEVOIX</u>	<u>LUCE</u>	<u>PRESQUE ISLE</u>
<u>CHEBOYGAN</u>	<u>MACKINAC</u>	<u>ROSCOMMON</u>
<u>CLARE</u>	<u>MANISTEE</u>	<u>SANILAC</u>
<u>CRAWFORD</u>	<u>MASON</u>	<u>SCHOOLCRAFT</u>
<u>EMMET</u>	<u>MONTCALM</u>	<u>TUSCOLA</u>
<u>GLADWIN</u>	<u>MONTMORENCY</u>	
<u>GOGEBIC</u>	<u>OCEANA</u>	

SOURCE:

65 F.R., P. 82238 (DECEMBER 27, 2000)
STATISTICAL POLICY OFFICE
OFFICE OF INFORMATION AND REGULATORY AFFAIRS
UNITED STATES OFFICE OF MANAGEMENT AND BUDGET